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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,388	11/21/2001	Wataru Morikawa	MORIKAWA4A	1349

7590 06/28/2005

BROWDY AND NEIMARK, P.L.L.C.  
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WASHINGTON, DC 20001-5303

EXAMINER
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HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1643

DATE MAILED: 06/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/989,388	MORIKAWA ET AL	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1642	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 April 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>03/15/03</u>  | 6) <input type="checkbox"/> Other: _____                                    |

9-0-2

**DETAILED ACTION**

***Response to Amendment***

1. Claims 1-4 are pending.  
Claims 1 and 2 have been amended.  
Claims 1-4 are examined on the merits.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Information Disclosure Statement***

3. The information disclosure statement filed July 15, 2003 has been considered in its entirety. Applicants did provide references, AD, AH, AK, AM, and AO

***Withdrawn Rejections***

***Claim Rejections - 35 USC § 112***

4. The rejection of claim 1 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of Applicants' listing the page and line number in the specification.
5. The rejection of claim 2 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition for inhibiting lung tumor metastasis and lung tumor growth, does not reasonably provide enablement for a composition for

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inhibiting any and all tumor metastasis and any and all tumor growth is withdrawn in light of Applicants' amendment.

6. The rejection of claims 1-4 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of Applicants' amendment.

***Maintained Rejection***

***Claim Rejections - 35 USC § 102***

7. The rejection of claims 1-4 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent number 5,288,489 (February 22, 1994/ IDS reference AA) is maintained.

Applicants submit, "...the process disclosed in Reich et al. is the same as the herein claimed process up to step (b)" and "...silent with respect to step (c)", see Remarks submitted April 12, 2005, page 9. Applicants also argue "...that Reich does not appreciate ...proteolysis of Lys-plasminogen with elastase provides of different fractions of fragments", see bridging sentence of page 9 and 10 of Remarks. In conclusion Applicants aver, "Reich et al. erroneously consider that the proteolysis produces a single molecular species..." and "...the product obtained by Reich et al. would never inhibit lung tumor metastasis and lung tumor growth, nor inherently have the molecular weight claimed herein, lack of glycosylation, or heparin binding activity.", see page 10. These arguments and points of view have been carefully considered, but are unpersuasive.

The patent discloses "...a fragment consisting of the proenzyme domain of plasminogen with a single attached kringle is generated, the remaining 4 kringles and intervening peptides having been separated.", see column 8, lines 52-58. The separation in itself implies fractions of fragments were generated and these fractions of fragments would bind heparin, thus anticipating Applicants' claimed invention. Applicants have not presented scientific data clearly distinguishing between the fragments of the prior art and those of Applicants. Moreover, the claims do not recite a binding assay. "[W]hich binds heparin" is only a characteristic which the fragment would necessarily possess.

Based on the analysis set forth in the preceding paragraphs including factual and technical grounds provided by the prior art the inherent features necessarily flow from the said art and the rejection stands.

### ***Conclusion***

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571) 272-0831. The examiner works a flexible schedule, however she can normally be reached between the hours of 6:30 am to 5:30 pm with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**ALANA M. HARRIS, PH.D.**  
**PRIMARY EXAMINER**



Alana M. Harris, Ph.D.  
22 June 2005